REMARKS

The Office Action dated July 23, 2003 has been carefully considered. Claims 1, 3, 4, 6, 8 and 42 have been amended. Claims 43-47 have been added. Claim 2 has been cancelled. Claims 1 and 3-48 are in this application.

The Examiner cited minor informalities. Applicants have amended the claims and specification to correct for the minor informalities.

The previously presented claims 3, 4, 6, 34 and 42 were rejected under 35 USC §112 as indefinite as including a broad range together with a narrow limitation. The claims were amended to obviate the Examiner's rejection.

The previously prosecuted claims 1, 3, 5-7, 9, 11, 14, 15, 18-24, 26, 27 and 30-36 were rejected under 35 U.S.C. § 102 as anticipated by PGPUB 2001/0007671 to Gueret ("Gueret '671").

Applicants point out that the present invention relates to a patch for controlled delivery of cosmetic, dermatological or pharmaceutical active ingredients onto the skin, hair follicles or sebaceous glands formed of a single layer of a bioadhesive water-soluble film-forming polymer. As described on page 5, lines 11-19, as the patch rests on the skin, delivery of the active ingredients is provided. The patch offers the advantages of an effective residence time with minimal discomfort and ease of use. The patch has additional advantages of no need to remove the patch, rinsing of the skin with water will remove any residue of the patch from the treatment site, no visible change area of the treatment area since the patch is invisible to the naked eye, ease of use for applying actives to the target site and controlled release of encapsulated actives.

Gueret '671 discloses a cosmetic, pharmaceutical or dermatological patch comprising a composition including a hydrophilic gelling system in an aqueous phase of at least one gellan gum and at least one other hydrocolloid.

In contrast to the invention defined by the present claims, Gueret '671 does not teach or suggest a patch formed of a bioadhesive water-soluble film-forming polymer. To the contrary, Gueret '671 teaches away from the present invention by teaching hydrophilic materials that gel in response to water. Accordingly, the patch disclosed by Gueret '671 is not water-soluble and does not dissolve or disintegrate upon application of moisture. Rather, the patch disclosed by Gueret

'671 stays intact onto the skin such that the patch does not disintegrate when it is removed from the skin.

Furthermore, in order to maintain the integrity of the patch, Gueret '671 teaches that the patch includes a reinforcing member to provide additional structural integrity to the patch such that the patch can be reused. In contrast, the patch of the present invention is not removed from the skin since it is formed of bioadhesive water soluble materials. The patch can be removed by rinsing with water (see page 16, lines 9-10 of the application). Accordingly, claims 1, 3, 5-7, 9, 11, 14, 15, 18-24, 26, 27 and 30-36 are not anticipated by Gueret '671.

The previously presented claims 1, 4-6, 8, 9, 11, 13-15, 18, 20-25, 27-37 and 42 were rejected under 35 USC §102(e) as anticipated by U.S. Patent No. 6,419,935 to Gueret ("Gueret '935").

Gueret '935 disclose a cosmetic skin treatment method in which a patch is configured to be used in both a cleansing mode and a treatment mode. The patch includes a polymeric matrix and a reinforcing member. When the cleansing mode is selected the patch is adhered to dry skin with an adhesive for a time sufficient to allow an impurity in the area of the skin to become attached to the polymeric matrix. After the impurity is attached, the patch is removed from the skin. When the treatment mode is selected, a cosmetically active agent is dissolved upon application of moisture and the patch is removed from the area of the skin.

In contrast to the invention defined by the present claims, Gueret '935 do not teach or suggest a patch formed of a bioadhesive water-soluble film forming polymer. Rather, Gueret '935 teach a patch formed of a reinforcing member and a silicone adhesive (see Col. 6, lines 1-5). Accordingly, the Gueret '935 patch does not dissolve upon contact with water. To the contrary, Gueret '935 teach that the patch maintains its integrity and is removed after cleansing or treatment steps (see claims 1 and 4).

Further, Gueret '935 teaches the use of a water absorbent compound to absorb moisture, thereby facilitating dissolving of a water-soluble active compound when a water-soluble active compound is present in the matrix (see col. 6, line 54-col. 7, line 11). The water soluble active compound can be polyvinyl alcohol, cellulose, starches, gelatin and casein. However, in contrast to the invention defined by the present claims, Gueret '935 do not teach or suggest that a water

soluble film is used to attach the patch to skin. Rather, the water soluble compound is used to activate a water-soluble active ingredient and the patch is held by an adhesive to the skin. Accordingly, the patches disclosed in Gueret '935 absorb water but do not dissolve in water. Thus, the invention defined by claims 1, 4-6, 8, 9, 11, 13-15, 18, 20-25, 27-37 and 42 is not anticipated by Gueret '935.

The previously presented claims 1, 3, 6, 8-14, 16-18, 22, 24, 26, 27, 30, 32 and 37-40 were rejected under 35 USC §102(e) as anticipated by U.S. Patent No. 6,586,000 to Luo et al.

Luo et al. disclose a drug delivery system including a drug reservoir containing a drug, a means for maintaining the system to the body surface and a backing layer. The drug reservoir may be a polymeric adhesive, hydrogel or may be a sealed pouch.

In contrast to the invention defined by the present claims, Luo et al. do not teach or suggest a patch formed of a single polymeric matrix material formed of a bioadhesive water-soluble film forming polymer. To the contrary, Luo et al. teaches a multilayer patch formed of a pressure sensitive adhesive reservoir comprising the active and a backing system. In contrast to the water-soluble film of the present invention, the Luo et al. patch is physically removed after the predetermined time (see col. 33, lines 40-48). Applicants submit that pressure sensitive adhesive patches have the drawback that they may cause damage of the treated skin area upon removal of the patches and cause skin irritation or leave adhesive residue on the skin. Further, Luo et al. includes a backing layer which is inert and incapable of absorbing drugs. In contrast, the water-soluble film forming polymer of the present invention in which the patch dissolves or disintegrates upon application of moisture. Accordingly, the invention defined by the present claims is not anticipated by Luo et al.

Claim 7 was rejected under 35 USC §103 as being obvious in view of Gueret '935 in combination with U.S. Patent No. 5,322,695 to Shah et al. or Luo et al. in combination with Shah et al.

Shah et al. disclose a multilayer pressure sensitive adhesive patch. The patch consists of a polymeric backing and adhering to one surface of the polymeric backing a medication reservoir.

In contrast to the invention defined by the present claims, Shah et al. do not teach or suggest a patch formed of a bioadhesive water-soluble film-forming polymer. Instead, Shah et al. teach away from the present invention by describing that this invention is directed to a moisture-vapor-permeable and oxygen-permeable adhesive dressing for use in supplying a topical medicament to human skin in a controlled release manner which dressing is unaffected by and impermeable to water in the liquid phase (see col. 6, lines 8-12). Thus, Shah et al. do not cure the deficiencies of Gueret '935 or Luo et al. noted above and the present invention is not obvious in view of Shah et al. in combination with Gueret '935 or Luo et al. since none of the references teach a patch formed of a bioadhesive water-soluble film-forming polymer.

Claim 41 was rejected under 35 USC §103 as obvious in view of Luo et al. in combination with Shah et al.

As described above, neither Luo et al. or Shah et al. describe or suggest a patch formed of a bioadhesive water-soluble film-forming polymer and the present invention is not obvious in view of the combination of Luo et al. and Shah et al.

In view of the foregoing, Applicants submit that all pending claims are in condition for allowance and request that all claims be allowed. The Examiner is invited to contact the undersigned should he believe that this would expedite prosecution of this application. It is believed that no fee is required. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,

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